**Questionnaire B4: Subpart B: §46.206 Fetal Material**

PI:  Protocol #

Completed by Primary Reviewer or Chair:

* *Provide justification as to how the proposed research meets the criteria for that each part.*

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| **Subpart B: Fetal Material** |
| §46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.  (a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities. [see below for Pennsylvania statute]  (b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable. [i.e. PARENTS of the FETUS] |
| **18 Pa.C.S. § 3216 (2004). Fetal experimentation.** |
| (a) Unborn or live child.--Any person who knowingly performs any type of nontherapeutic experimentation or nontherapeutic medical procedure (except an abortion as defined in this chapter) upon any unborn child, or upon any child born alive during the course of an abortion, commits a felony of the third degree. "Nontherapeutic" means that which is not intended to preserve the life or health of the child upon whom it is performed. |
| (b) Dead child.--The following standards govern the procurement and use of any fetal tissue or organ which is used in animal or human transplantation, research or experimentation:  1. No fetal tissue or organs may be procured or used without the written consent of the mother. No consideration of any kind for such consent may be offered or given. Further, if the tissue or organs are being derived from abortion, such consent shall be valid only if obtained after the decision to abort has been made.  Written consent of the mother obtained. |
| 2. No person who provides the information required by section 3205 (relating to informed consent) shall employ the possibility of the use of aborted fetal tissue or organs as an inducement to a pregnant woman to undergo abortion except that payment for reasonable expenses occasioned by the actual retrieval, storage, preparation and transportation of the tissues is permitted. |
| 3. No remuneration, compensation or other consideration may be paid to any person or organization in connection with the procurement of fetal tissue or organs.  No remuneration was paid for the procurement of the fetal tissue or organs used in this research. |
| 4. All persons who participate in the procurement, use or transplantation of fetal tissue or organs, including the recipients of such tissue or organs, shall be informed as to whether the particular tissue or organ involved was procured as a result of either:  (i) stillbirth; (ii) miscarriage; (iii) ectopic pregnancy;  (iv) abortion; or  (v) any other means. Specify: |
| 5. No person who consents to the procurement or use of any fetal tissue or organ may designate the recipient of that tissue or organ, nor shall any other person or organization act to fulfill that designation.  No recipient designated. |
| **Additional comments:**  **Reviewed By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |